

**DR. B. C. ROY COLLEGE OF PHARMACY & AHS, DURGAPUR  
(NBA Accredited for UG Pharmacy Program)**

**FACULTY: Dr. Aniruddha Mukherjee (AM)**

**PROGRAM: M. PHARM**

**Semester: 2nd**  
**Course Code: MPT - 2082**  
**Course Name: Pharmacological and Toxicological Screening Methods-II**

**-: Syllabus :-**

1.

Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive)

Regulatory guidelines for conducting toxicity studies

OECD, ICH, EPA and Schedule Y, OECD principles of Good laboratory practice (GLP),

History, concept and its importance in drug development

2

Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines.

Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies.

Test item characterization- importance and methods in regulatory toxicology studies

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**Supplementary Materials for Reference and Self Study:**

Date	Module (as per Lesson Plan)	Topic	Live Recording Link	Powerpoint Presentation Link	Supplementary Notes / Resources	Remarks
16-04-21	1	Discussion on syllabus and introduction of the need of the subject	<a href="#">Youtube</a>	-----		-----
23-04-21	1	Acute Toxicity studies OECD	<a href="#">Youtube</a>	<a href="#">PPT</a>		First read the guidelines
07-05-21	1	Fundamentals of toxicology	<a href="#">Youtube</a>	<a href="#">PPT</a>	<a href="#">Guideline</a>	
14-05-21	1	EPA guideline	<a href="#">Youtube</a>	<a href="#">PPT</a>	<a href="#">Articles</a>	
	1	ICH guidelines	<a href="#">Youtube</a>	<a href="#">PPT</a>	<a href="#">Articles</a>	
	1	OECD Articles	<a href="#">Youtube</a>	<a href="#">PPT</a>	<a href="#">Articles</a>	
21-07-21	1	Good laboratory practice (GLP)	<a href="#">Youtube</a>	<a href="#">PPT</a>	<a href="#">Articles</a>	
	1	Schedule Y	<a href="#">Youtube</a>	<a href="#">PPT</a>	<a href="#">Articles</a>	
01-06-21	2	The fixed dose procedure (FDP):- OECD 420	<a href="#">Youtube</a>	<a href="#">PPT</a>	<a href="#">Guideline 420</a> <a href="#">Guidance document</a> <a href="#">GHS category</a>	<a href="#">Article</a>
14-06-21	1	ICH guideline	<a href="#">Youtube</a>	<a href="#">PPT</a>	<a href="#">Guideline</a>	
18-06-21	2	Determination of acute oral toxicity (LD50) & Acute toxicity study - OECD-423	<a href="#">Youtube</a>	<a href="#">Determination of acute oral toxicity (LD50) - PPT</a> <a href="#">Acute toxicity study - OECD-423 PPT</a>	<a href="#">Articles</a>	
09-07-21	2	Acute toxicity testing for topical preparations & ocular preparations  Acute oral toxicity OECD 425	<a href="#">Youtube</a>	<a href="#">Topical preparations</a>  <a href="#">Ocular preparations</a>	<a href="#">Articles - OECD 425</a>	<a href="#">OECD 425</a>

23-07-21	2	Sub-acute – oral toxicity studies (OECD guidelines)	<a href="#">Recorded class</a>	<a href="#">PPT</a>	<a href="#">Articles</a>	<a href="#">Guideline - 407</a>
30-07-21	2	Chronic – oral toxicity studies (OECD guidelines)	<a href="#">Youtube</a>	<a href="#">PPT</a>	<a href="#">Articles</a> <a href="#">Benchmark</a>	<a href="#">Guideline</a> <a href="#">References</a>
06-08-21	2	Dermal toxicity	<a href="#">PPT</a>	<a href="#">Guideline</a>	<a href="#">References</a>	<a href="#">Articles</a>
06-08-21	2	Skin sensitisation test (LLNA - OECD)	<a href="#">Guideline</a>	<a href="#">References</a>	<a href="#">Articles</a>	
	5	Toxicokinetics	<a href="#">Guideline</a>	<a href="#">Articles</a>		
	5	Toxicokinetics in preclinical evaluation	<a href="#">Materials</a>			
	5	Saturation kinetics Importance and applications of toxicokinetic studies	<a href="#">Youtube link</a>	<a href="#">Articles</a>	<a href="#">PPT - I</a> <a href="#">PPT - II</a>	<a href="#">Video - I</a> <a href="#">Video - II</a> <a href="#">Video - III</a>
	5	Alternative methods to animal toxicity testing	<a href="#">Articles</a>		<a href="#">Useful links - I</a> <a href="#">Useful links - II</a> <a href="#">Useful links - III</a>	<a href="#">Video - I</a> <a href="#">Video - II</a>

